DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1262]

Improving Premarket Review and Approval of Food and Color Additives in the Center for Food Safety and Applied Nutrition; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting public comment on ways to improve the process of premarket review and approval of food and color additive petitions by FDA's Center for Food Safety and Applied Nutrition (CFSAN). CFSAN received substantial new resources for fiscal year 2000 targeted to the premarket review of petitions for approval of new uses of food and color additives. This document is being published to give all interested parties an opportunity to comment on how these new resources may best be applied to address public health issues related to the timely approval and safe use of food and color additives. CFSAN will consider administrative and procedural enhancements to ensure that program goals are met while maintaining high standards of safety and scientific credibility.

DATES: Submit written comments by [*insert date 75 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Alan M. Rulis, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3100, e-mail: arulis@cfsan.fda.gov.

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SUPPLEMENTARY INFORMATION: The Office of Premarket Approval (OPA) in CFSAN manages the following programs: Petitions for new uses of food and color additives, consultations on foods developed using new methods of biotechnology, generally recognized as safe (GRAS) notices, threshold of regulation (TOR) exemption requests, and premarket notifications for food contact substances (PMN). In addition to these programs, OPA is the lead technical authority for food additives for the U.S. Government. OPA provides expertise and leadership in the international forums of the Joint Food Agricultural Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives, the North American Free Trade Agreement, and the Codex Alimentarius Commission to define international standards, promote harmonization, and evaluate equivalency agreements for food additives and other food ingredients. OPA also has laboratory research and sample analysis components that provide technical support for the enforcement of the food additive regulations.

The current process of reviewing food and color additive petitions has evolved over 40 years since the passage of the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (the act). Approvals of food and color additives have been based on a critical scientific evaluation of safety information submitted by petitioners. The primary components of this evaluation are the review of chemical, toxicological, and environmental scientific data and information and an estimation of the probable human dietary exposure to additives. During its review of safety of new food additive uses, OPA develops an administrative record that relies on scientific data and information to support the agency's safety conclusions. Although this framework has a high level of scientific credibility, CFSAN recognizes that improvements could be made to ensure that the process is more efficient while maintaining the current high scientific standards. With this notice, CFSAN is soliciting comments on ways to improve the timeliness, transparency, and predictability of its review of food and color additive petitions, and its monitoring of the safety of food and color additives over time.

To help focus comments, FDA requests that comments regarding food and color additive review address the following:

1. The act requires that the agency base its safety decisions for the premarket review of additives on ''a fair evaluation of the data'' and requires that new uses of food additives be consistent with the agency safety standard of ''reasonable certainty of no harm.'' What specific changes can be made to the current review process to make that process more efficient, i.e., transparent, timely, responsive, and predictable, while preserving these high standards of data review and of safety?

2. On January 5, 1999 (64 FR 517), CFSAN made available a guidance describing a policy to expedite the review of petitions for food additives that are intended to significantly decrease human pathogens or their toxins in/on food. Should the Center consider broadening the criteria for eligibility for such expedited petition review? If so, petitions for what types of uses should be added?

3. How should the increased appropriation to CFSAN that is targeted for the safety review of food and color additives be allocated? For example, to what extent should new resources be allocated to: (1) Performing prefiling consultations with prospective applicants for new uses of food ingredients, (2) adding personnel resources to the review process, (3) enhancing electronic data management systems such as automated workflow management or data warehousing, and (4) acquiring or monitoring new safety information on already approved additives?

4. What specific program enhancements should be given the highest priority?

Interested persons may, on or before [*insert date 75 days after date of publication in the* **Federal Register**], submit to the Dockets Management Branch (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals

may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 4/28/00

April 28, 2000

Margaret M. Dotzel
Acting Associate Commissioner for Policy

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Suzette N. Reese